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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,283	01/13/1999	DAVID E. FISCHER	48012	7211

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/229,283	FISCHER, DAVID E.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,4,13,14 and 16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1, 4, 13-14, 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 31, 2006 are acknowledged and have been entered. Claims 14 and 18 have been amended. An action on the RCE follows.

2 Claims 1, 4, 13, 16-23 are pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4, The following rejections are being maintained:

Claim Rejections - 35 USC 112

5. Claims 1, 4, 13, 18-20, 22-23 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed October 19, 2005.

Applicant argues that the case law cited by Examiner refers to nucleic acid inventions and that the instant application is drawn to antibodies which are defined differently in the art. The argument has been considered but has not been found persuasive because the case law cited by Examiner has established the principles required for satisfaction of the written description requirement of 35 USC 112 and for the reasons of record, the specification does not meet those requirements.

Applicant cites Capon v. Eshhar and argues that the Court distinguished Lilly from Eshhar wherein the discovery in Lilly was the function of a gene and therefore its DNA sequence was critical. In Eshhar, the discovery was not gene

function, but rather the use of a particular combination of genes and thus the Court held that the DNA structure in Eshhar was not necessary. Similarly, here, the involved claims are directed to a diagnostic method utilizing an antibody, not the discovery of the antibody itself.

The argument has been considered but has not been found persuasive because there appears to be no nexus between the instantly claimed invention and the case law cited by Applicant. Although Applicant states that the Court ruled that the DNA structure in Eshhar was not necessary, Applicant neglects to include the critical element of the decision, that is, that the DNA structure in Eshhar was not necessary because it was already known in the art. Further, the claims in the Eshhar case are not drawn to the use of a particular combination of genes, but rather are drawn to chimeric molecules. Given the above, although Applicant points to a similarity between the claims of the instant invention and the claims reviewed in the Eshhar case, Examiner fails to see any similarity between the two cases. In particular, unlike the known structure of the Eshhar claims, the structure of the broadly claimed selective antibodies is unknown because the epitopes to which they bind, other than the N-terminal Taq-Sac fragment of human Mi, are unknown. Similar to the Lilly case, the broadly claimed, unknown structures are critical to the instant invention. Thus, the citation, by Examiner of Lilly is appropriate. Further, although the Court distinguished Lilly from Eshhar, the findings of the Court support Examiner's finding of a lack of written description in the instant case. In particular, the Court specifically stated that the citation of the Lilly case was inappropriate because unlike the claimed invention in Eshhar, the cDNA for human insulin had never been characterized (see page 8, column 1 of the decision). Further, the Court stated that it is appropriate to recognize the

variability in the science in determining the scope of coverage to which the inventor is entitled and that the decision as to whether the claimed scope is appropriate usually focuses on the exemplification in the specification and the Court pointed specifically to Lilly and stated that the genus is not described where "a representative number of cDNAs defined by nucleotide sequence, falling within in the scope of the genus" had not been provided. Similar to the Lilly case, a representative number of antibodies which bind selectively to Mi, other than those that bind to the single disclosed site of the N-terminus Taq-Sac fragment of Mi, falling within the scope of the genus has not been provided.

Applicant further argues that (a) Applicant was in possession of an antibody which selectively binds human Mi in the N-terminus Taq-Sac fragment of Mi, (b) the examples detail the methods by which the antibody was created and validated and the skilled artisan, would be able to produce antibodies that selectively bind human Mi.

The argument has been considered but has not been found persuasive because (a') possession of an antibody that selectively binds human Mi in the N-terminus Taq-Sac fragment of Mi does not provide a written description for the broadly claimed antibody, for the reasons of record. (b') a review of the examples drawn to the production of the selective antibody reveals that monoclonal antibody D5 was raised against a histidine fusion protein expressed from the amino terminal Taq-Sac fragment of human MITF (p. 14), reveals that Mi antibodies were generated against the N-terminus Taq-Sac fragment of human Mi (p. 16), reveals that antibodies may be raised against either a peptide of Mi or the whole molecule and that preferred peptides include regions unique to Mi (p. 13). However, other than a teaching that the preferred peptides include regions unique to Mi, there is no

guidance as to what regions these may be or where they are located on the protein. In the absence of such teaching, one must conclude that the claims are drawn to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant further argues that genetic manipulation of antibody genes was routine to those of skill in the art as of the effective filing date of the present application and attaches abstracts published prior to the filing date of the present application that detail that a description of function defines an antibody to the skilled artisan because they know its critical characteristics. The argument and the abstracts have been considered but have not been found persuasive because in the absence of the guidance on, or teaching of, the critical feature defining the claimed antibody, that is the epitope to which the selective antibody binds, the antibody is not defined. The disclosure of the single "unique' site does not provide a written description of the broadly claimed antibody.

Applicant further argues that methods are taught in the instant application to test whether an antibody would function in its intended use (i.e. diagnostically) and points specifically to page 19, lines 25-34 and thus the present description provides a written description of the claimed invention. The argument has been considered but has not been found persuasive because a review of page 19, lines 25-34 reveals only the failure of Mi monoclonal antibody D5 to cross-react with other b-HLH-Zip factors and its use in Western blot, immunofluorescence and immunohistochemistry, Thus, it appears that Applicant is arguing that antibodies may be screened/tested for the claimed activity. However, Applicant's suggestion that the claimed antibody can be identified through testing/screening does not

provide a written description of the claimed invention given that, the court has found (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays are merely a wish or plan for obtaining the claimed chemical invention. Given that the Court views screening assays as a wish or a plan for obtaining an invention, it is clear that Applicant was not in possession of the claimed invention at the time the application was filed.

Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. Claim 21 appears to be free of the art but is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

7. Claims 14, 16-17 appear to be allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
April 7, 2006